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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,507	03/01/2004	Albert Pierce	14435-004001/ VPI/03-12	1051
26161 7590 03/22/2007 FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER ZHOU, SHUBO	
			ART UNIT	PAPER NUMBER
			1631	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/790,507

Applicant(s)

PIERCE ET AL.

Examiner

Shubo (Joe) Zhou

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 40 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 and 42-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 July 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 5/2/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Amendments

Applicants' election, without traverse, of Group I (claims 1-39 and 42-44) in the response filed 12/29/06 is acknowledged. The preliminary amendment to the specification filed 7/19/04 is acknowledged and entered.

Claims 1-44 are currently pending, and claims 1-39 and 42-44 are under examination. Claims 40-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/29/06.

Information Disclosure Statement

The Information Disclosure Statement filed 5/2/05 has been entered and documents therein have been considered. Initialed copies of the form PTO-1449 are enclosed herein.

Drawings

It is noted that replacement sheets of the drawings were filed 7/19/04. 37 CFR 1.121(d) requires:

Drawings : One or more application drawings shall be amended in the following manner: Any changes to an application drawing must be in compliance with § 1.84 and must be submitted on a replacement sheet of drawings which shall be an attachment to the amendment document and, in the top margin, labeled "Replacement Sheet". Any replacement sheet of drawings shall include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is amended. Any new sheet of drawings containing an additional figure must be labeled in the top margin as "New Sheet". All changes to the drawings

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shall be explained, in detail, in either the drawing amendment or remarks section of the amendment paper.

The amended drawings filed 7/19/04 are not completely compliant with 37 CFR 1.121(d) as not being labeled "Replacement Sheet."

Specification

The specification is objected to because of the following including informalities:

Trademarks are used in this application, such as PERL on page 22. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The disclosure is objected to also because it contains an embedded hyperlink and/or other form or browser-executable code. Such code is present in the specification at page 16 and elsewhere. Applicants are required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP ' 608.01.

Applicant is reminded of the proper content of an abstract of the disclosure. A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for

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making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

In the instant case, the elected invention is drawn to a method process for modeling complex formation between a query ligand and a target macromolecule. The abstract filed 2/12/04, however, only contains one sentence: "Methods of target ligand generation are disclosed" without setting out the steps of the method process.

Appropriate correction is required.

Claim Rejections-35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-39 and 42-44 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are drawn to a computer process or apparatus comprising computer programs for executing the process, the process comprising: (1) providing a set of models, wherein each model comprises three-dimensional structural information for a ligand or ligand/macromolecule complex; wherein each model is related to the other models of the set by a homologous structural feature; (2) mapping spatial relationships between the models such that the models are superimposed with respect to the homologous structural feature; (3) identifying one or more pairs of matching bonds between ligands of the set, wherein the matching bonds comprise a bond of a first ligand (B 1) and a bond of a second ligand (B2) that are superimposed in step (2) such that (i) an atom at each end of the bond (B1) is within 1.8 angstrom of an atom at each end of the bond (B2), (ii) the bond (B1) and the corresponding bond (B2) are of the same bond order, and (iii) the bond (B1) and the corresponding bond (B2) are related by an angle of 30° or less; (4) selecting a plurality of subsets of atoms and/or bonds from each ligand; wherein each subset comprises a bond and/or, an atom connected to the matching bond; (5) generating output ligands, each output ligand comprising atoms and/or bonds of a first subset and atoms and/or bonds of a second subset, wherein the first subset and the second subset comprise atoms and/or bonds derived from opposite ends of the matching bond.

The following analysis of facts of this particular patent application follows the rationale suggested in the "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (OG Notices: 22 November 2005, available from the US PTO website at <http://www.uspto.gov/web/offices/com/sol/og/2005/week47/og200547.htm>).

The Guidelines states:

To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways (Guidelines, p. 19):

- *The claimed invention "transforms" an article or physical object to a different state or thing.*
- *The claimed invention otherwise produces a useful, concrete and tangible result, based on the factors discussed below.*

In the instant case, at least one embodiment of the claimed invention merely manipulates structural data of molecule and performs a series of calculations for molecular modeling. Thus, the process does not appear to transform an article or physical object to a different state or thing outside a computation device.

Furthermore, the invention does not produce a useful, concrete and tangible result. Specifically it does not produce a tangible result. Since the process, at least for one embodiment of the claimed invention, merely manipulates molecular structural data and performs a series of calculations for modeling entirely in the confine of a computational device without using or making available for use the results of the data manipulation to enable its functionality and usefulness to be realized. While step 5) generates output ligands, there is no clear indication that the modeled ligands are outputted to a user to use the results of the data manipulation.

Claim Rejections-35 USC § 112

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-39 and 42-44 are rejected under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 in step (1) recites a “a set of models, wherein each model comprises three-dimensional structural information ... wherein each model is related to the other models of the set by a homologous structural feature.” The term "homologous" is a relative term that renders the

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claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. When the 3-D structures of two molecules are compared, some part of the molecules might share the same atoms at corresponding positions, and some different atoms might share the same spatial shape or form. Without an explicit standard or criteria for determining whether two structures are homologous, it would not be clear to one skilled in the art what structures are homologous and what are not.

The metes and bounds of the claimed inventions in other claims reciting homologous structural feature, such as claim 39, are unclear, and the claims are thus rejected for the same reasons set forth above.

Step (4) of claim 1 recites the phrase “subset of atoms and/or bonds from each ligand.” The phrase lacks adequate antecedent basis because there is no prior reference to a set of atoms and/or bonds from each ligand, and therefore it is unclear as to where the subset should be derived.

The phrase “the matching bond” recited in step (4) of claim 1 lacks adequate antecedent basis. There is prior reference to multiple “matching bonds” in step (3) and thus it is unclear which singular matching bond of the plurality of matching bonds is referred to in step (4).

The phrase “the matching bond” recited in step (5) of claim 1 lacks adequate antecedent basis. There is prior reference to multiple “matching bonds” in step (3) and thus it is unclear which singular matching bond of the plurality of matching bonds is referred to in step (5).

Step (5) of claim 1 recites the phrase “a first subset” of atoms and/or bonds and “a second subset” of atoms and/or bonds. The phrases “first subset” and “second subset” lack adequate antecedent basis because there is no prior reference to a set of atoms and/or bonds from each ligand, and therefore it is unclear as to where the subsets should be derived.

Claims 39 and 42-44 are rejected as containing the same indefinite limitations as those in claim 1 as set forth above.

Claim 10 recites “[t]he method of claim 1, wherein the ligand is a small molecule.” The phrase “the ligand” lacks clear antecedent basis because there are multiple ligands recited in claim 1: “a ligand” recited in line 2 and “ligands” in step (5), and thus it is not clear which singular ligand of the plurality of ligands from claim 1 is referred to in claim 10.

Claim 30 recites “obtaining a composition comprising a compound corresponding to a ligand from a subset of output models.” The term “corresponding” makes the claim indefinite because it is not clear in what way the compound has to correspond to the ligand. For example, is the compound the ligand itself? Or does the compound bind to the ligand?

The phrase “the evaluating comprises ...” recited in claim 32 lacks clear antecedent basis because there are at least two evaluating steps in claim 31, from which claim 32 depends, including “evaluating the output models” recited in claim 28, from which claim 32 indirectly depend, and “evaluating the composition” recited in claim 31. Thus it is not clear which evaluating step is referred to in claim 32.

Claim 35 recites “a ligand provided in the previous step (2) of the repetition.” The metes and bounds of the claimed invention are unclear because step (2) does not provide any ligand, but it is a mapping step. Is the ligand provided in step (1) intended?

Claim 38 recites “wherein the ligands comprise a macrocyclic moiety, and wherein at least two matching bonds are identified within the macrocycle of each ligand.” The metes and bounds of the meaning of the limitation “two matching bonds” are not clear. Is it two matching bonds between the ligand and other ligands, or between the ligand and its corresponding macromolecule to which the ligand binds.

Clarification of the metes and bounds of the claims is requested.

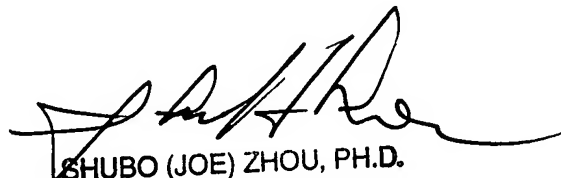
Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem (Remy) Yucel, Ph.D., can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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